



## REMARKS

This Response is submitted in response to the Office Action mailed on January 13, 2003.

Pursuant to the Office Action, Applicants are required to elect between one of six groups of alleged inventions: Group I (Claims 1-7); Group II (Claims 8-23); Group III (Claims 24-27); Group IV (Claims 28-32); Group V (Claims 31-41); and Group VI (Claims 42-46). Applicants elect, without traverse, Group II (Claims 8-23). Applicants however reserve the right to file divisional applications to the non-elected claims.

The only rejection of Claims 8-23 is in view of U.S. Patent No. 6,355,265 under the judicially-created doctrine of obviousness-type double patenting. Applicants are submitting herewith a terminal disclaimer with respect to that patent. Therefore, Applicants respectfully submit that there are no rejections pending against Claims 8-23 and accordingly Applicants request that these claims and the application be passed to allowance. In this regard, the non-elected claims have been canceled, i.e., Claims 1-7 and Claims 24-46.

The Patent Office has also requested that Applicants provide copies of the claims of co-pending Application Serial Nos. 09/759,561 and 10/044,113. Enclosed are the claims for those applications; the allowed claims for 09/759,561 and claims as filed for 10/044/113. Applicants note for the record that 09/759,561 was already of record in view of the Information Disclosure Statement Applicants filed on July 10, 2002.

Applicants also note that the following pending patent applications assigned to Applicants relate to the delivery of medicament that includes utilizing a chewing gum, gum base, or compressible center that is coated.

09/956,445  
09/759,838  
09/955,870  
09/990,628  
10/044,113

10/206,492

10/050,470

To the extent the Patent Office requires copies of these applications or the claims of same, please contact Applicants' undersigned attorney.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 1-7 and 24-46 have been canceled without prejudice or disclaimer.



**Allowed Claims for Serial No.: 09/759,561**

1. A method for delivering a medicament to an individual comprising the steps of:  
providing a chewing gum that includes a gum center and a coating that substantially surrounds the center, the coating comprising at least 50% by weight of the chewing gum, the coating comprising a medicament;

chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual; and

continuing to chew the chewing gum thereby creating a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

2. The method of Claim 1 wherein the coating includes a high-intensity sweetener.

3. The method of Claim 2 wherein the high-intensity sweetener is selected from the group consisting of aspartame, sucralose, saccharin, and acesulfame-k.

4. The method of Claim 1 wherein the coating is produced by alternating layers of a powder and a syrup onto the gum center.

5. The method of Claim 1 wherein the gum center includes at least 50% by weight water-insoluble gum base.

6. The method of Claim 1 wherein the medicament is selected from the group consisting of analgesics, muscle relaxants, antibiotics, antivirals, antihistamines, decongestants, anti-inflammatories, antacids, psychotherapeutic agents, insulin, vitamins, minerals, and cardiovascular agents.

7. The method of Claim 1 wherein the coating has a matte finish.

8. The method of Claim 1 wherein the coating does not include a shellac layer.

27. A method for reducing the amount of agent necessary to achieve an effect in an individual as compared a typical agent that is swallowed comprising the steps of:

providing a chewing gum comprising a gum center and a coating that substantially surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum, the coating comprising an agent that is typically swallowed by an individual to achieve a specific effect, the chewing gum comprising less than the typical amount of agent that is swallowed by the individual to achieve the effect;

chewing the chewing gum and thereby causing the agent to be released into the saliva of the individual; and

continuing to chew the chewing gum forcing the agent through an oral mucosa contained in a buccal cavity of the individual.

28. The method of Claim 27 wherein the agent is a medicament.

29. The method of Claim 27 wherein the medicament is selected from the group consisting of analgesics, muscle relaxants, antibiotics, antivirals, antihistamines, decongestants, anti-inflammatories, antacids, psychotherapeutic agents, and cardiovascular agents.

30. The method of Claim 27 wherein the gum center includes at least 50% by weight water-insoluble gum base.

31. The method of Claim 27 wherein the agent is a stimulant.

32. A method of enhancing an individual's performance comprising the steps of:

providing a chewing gum having a gum center and a coating that substantially surrounds the center, the coating comprising at least 50% by weight of the chewing gum, the coating comprising a performance enhancing amount of caffeine; and

chewing the chewing gum not more than ten minutes before the performance.

33. The method of Claim 32 wherein the performance to be enhanced is athletic.

34. The method of Claim 32 wherein the performance to be enhanced is cognitive.
35. The method of Claim 32 wherein the performance to be enhanced is alertness.
36. The method of Claim 32 wherein the chewing gum is chewed five minutes or less before the performance.
37. A method of delivering a medicament comprising the steps of:
- providing a chewing gum having a gum center and a coating that substantially surrounds the center, the coating comprising at least 50% by weight of the chewing gum, the coating comprising a medicament and not comprising a shellac layer; and
- chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum.
38. The method of Claim 37 wherein the medicament is selected from the group consisting of analgesics, muscle relaxants, antibiotics, antivirals, antihistamines, decongestants, anti-inflammatories, antacids, psychotherapeutic agents, and cardiovascular agents.
39. The method of Claim 37 wherein the gum center comprises approximately 30% to about 90% by weight insoluble gum base.
40. A method of increasing the stimulatory effect of a stimulant that has been previously swallowed by an individual comprising the steps of:
- providing a chewing gum having a gum center and a coating that substantially surrounds the center, the coating comprising at least 50% by weight of the chewing gum, the coating containing a stimulant and not having a shellac layer; and
- chewing the chewing gum causing the stimulant to be released by the chewing gum and forced into an oral mucosa located in a buccal cavity of the individual.
41. The method of Claim 40 wherein the stimulant is caffeine.

42. The method of Claim 40 wherein the gum center includes at least 50% by weight water-insoluble gum base.

43. A method for delivering a medicament to an individual comprising the steps of:

providing a chewing gum product that includes a gum center that is substantially coated by a formulation that includes a medicament and a sufficient amount of a masking agent to provide acceptable organoleptic properties, the formulation comprising at least 50% by weight of the chewing gum product; and

chewing the chewing gum product to cause the medicament to be released from the formulation into a buccal cavity of the individual.

44. The method of Claim 43 wherein the formulation includes a high-intensity sweetener.

45. The method of Claim 43 wherein the medicament is selected from the group consisting of analgesics, muscle relaxants, antibiotics, antivirals, stimulants, antihistamines, decongestants, anti-inflammatories, antacids, psychotherapeutic agents, insulin, vitamins, minerals, and cardiovascular agents.

46. The method of Claim 43 wherein the taste masking agent is selected from the group consisting of zinc gluconate, ethyl maltol, glycine, acesulfame-k, aspartame, saccharin, fructose, xylitol, isomalt, maltitol, spray dried licorice root, glycyrrhizine, sodium gluconate, glucono delta-lactone, vanillin, dextrose, sucralose, and ethyl maltol.

47. The method of Claim 46 wherein the masking agent comprises approximately 30% to about 99% by weight of the coating.

48. A method of manufacturing a medicament containing product comprising the steps of:

preparing a gum center having water soluble portion and a water insoluble; and coating the center by placing alternating layers of a powder and a syrup on the center to create a coated product, at least one of the powder or syrup layers comprising a medicament; and

the coated product comprising at least 50% by weight syrup and powder coating.

49. The method of Claim 48 wherein the gum center includes at least 50% by weight water-insoluble gum base.

50. The method of Claim 48 wherein the coating includes a high-intensity sweetener.

51. The method of Claim 48 wherein the medicament is selected from the group consisting of analgesics, muscle relaxants, antibiotics, antivirals, antihistamines, decongestants, anti-inflammatories, antacids, psychotherapeutic agents, insulin, vitamins, minerals, and cardiovascular agents.

52. The method of Claim 48 wherein at least two alternating layers are coated on to the center.

53. The method of Claim 48 wherein the powder comprises at least 70% by weight of the coating.

54. The method of Claim 48 wherein the coating does not include a shellac layer.





**Claims as Filed for Serial No.: 10/044,113**

1. A method for delivering a medicament to an individual comprising the steps of:  
  
providing a product that includes a consumable center and a coating that substantially surrounds the consumable center, the coating containing a medicament and comprising at least 50% by weight of the product; and  
  
placing the product in the mouth of the individual and causing the medicament to be released from the product into the buccal cavity of the individual.
2. The method of Claim 1 wherein the coating includes a high-intensity sweetener.
3. The method of Claim 1 wherein the high-intensity sweetener is chosen from the group consisting of aspartame, sucralose, saccharin, and acesulfame-k.
4. The method of Claim 1 wherein the coating is produced by alternating layers of a powder and a syrup onto the tableted center.
5. The method of Claim 1 wherein the consumable center is selected from the group consisting of a gummi confectionary, hard confectionary, confectionary starch, compressible sacharides, and compressible sugar alcohols.
6. The method of Claim 1 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; vitamins; minerals; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.
7. The method of Claim 1 wherein the coating has a polished finish.
8. A product including a medicament comprising:  
  
a consumable center; and

17. The product of Claim 16 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; vitamins; minerals; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

18. The product of Claim 16 wherein the consumable center is selected from the group consisting of hard confectionaries, gummi confectionaries, confectionary starches, and compressible excipients.

19. The product of Claim 16 wherein a taste masking agent comprises approximately 30% to about 99% by weight of the coating.

20. The product of Claim 16 wherein the coating includes approximately 0.1% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

21. A method of delivering a medicament comprising the steps of:

providing a product having a consumable center and a coating that substantially surrounds the center, the center comprising at least one compressible excipient and the coating including a medicament and comprising at least 50% by weight of the product; and

chewing the product to release the medicament into a buccal cavity of an individual chewing the product.

22. The method of Claim 21 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; nutraceuticals; nutritional supplements; diuretics; vitamins; minerals; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

23. The product of Claim 21 wherein the consumable center is selected from the group consisting of hard confectionaries, gummi confectionaries, confectionary starches, and compressible excipients.

24. A method of manufacturing a product containing an agent comprising the steps of:

preparing a center by tableting a consumable product to produce a tableted consumable center; and

coating the tableted consumable center by placing alternating layers of a powder and a syrup on the center to create a coated product, at least one of the powder or syrup layers including at least one agent.

25. The method of Claim 24 wherein the coated product comprises at least 50% by weight syrup and powder coating.

26. The method of Claim 24 wherein the tableted consumable center includes at least one compressible excipient chosen from the group consisting of saccharides and sugar alcohols.

27. The method of Claim 24 wherein the coating includes a high-intensity sweetener.

28. The method of Claim 24 wherein the agent is a medicament.

29. The method of Claim 28 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; vitamins; minerals; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

30. The method of Claim 24 wherein at least two alternating layers are coated on to the tableted consumable center.

31. The method of Claim 24 wherein the powder comprises at least 70% by weight of the coating.

32. A method of delivering a medicament comprising the steps of:

providing a product including a consumable center having a predefined shape and a coating that surrounds the center that includes a medicament; and

chewing the product for a sufficient time to cause a majority of the medicament to be absorbed by a buccal cavity of the consumer.

33. The method of Claim 32 wherein the product comprises at least 50% by weight syrup and powder coating.

34. The method of Claim 32 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; nutraceuticals; nutritional supplements; diuretics; vitamins; minerals; anesthetics; antitussives; bioengineered pharmaceuticals; and cardiovascular agents.

35. The method of Claim 32 wherein the coating includes a high-intensity sweetener.